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| APPLICATION NO.                                                       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|-----------------------------------------------------------------------|-------------|----------------------|--------------------------|------------------|
| 10/684,995                                                            | 10/14/2003  | Kathleen Heaney      | AM 100929                | 4725             |
| 25291                                                                 | 7590        | 12/31/2009           |                          |                  |
| WYETH LLC<br>PATENT LAW GROUP<br>5 GIRALDA FARMS<br>MADISON, NJ 07940 |             |                      | EXAMINER<br>LEVY, NEIL S |                  |
|                                                                       |             |                      | ART UNIT                 | PAPER NUMBER     |
|                                                                       |             |                      | 1615                     |                  |
|                                                                       |             |                      | MAIL DATE                | DELIVERY MODE    |
|                                                                       |             |                      | 12/31/2009               | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/684,995 | <b>Applicant(s)</b><br>HEANEY ET AL. |  |
|                              | <b>Examiner</b><br>NEIL LEVY         | <b>Art Unit</b><br>1615              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46,47,49,50 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46 is/are allowed.
- 6) ☒ Claim(s) 46,47,49,50 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 112 rejection is dropped.

### ***Claim Rejections - 35 USC § 103***

Claims 50,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over TREACY et al WO 0054591

amitraz and metaflumizone at 10/1, 1/1, and 1/10 are shown at Table 1 and at page 13, lines 12-16. Actives can be at 50% (1/1 in acetone, lines 13, P. 15).

Contrary to applicant's arguments of low concentrations of actives, Example 2 shows the low concentrations to be 100% effective at only 0.5 of instant compound Ia and 1% of the second compound. Who would ask for anything more? The pesticide formulator would be quite able to prepare higher concentrations of actives, of the few second actives of Table I, with formula Ia, with minimal testing to determine the concentrations required to provide optimal mortality of the pest of concern. Thus, the compositions of TREACY provide prima facie obviousness over the instant claims.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use the synergistic combination shown particularly effective by TREACY to control flies, since TREACY does include these pests in the pronouncements of pests efficaciously controlled.

The insecticide formulator would find it obvious and within her purview to adjust the carrier/active ratio to optimize degree of kill, reduction in non-target toxicity and to selection of the solvent and additive actives to achieve optimal results against the pest species of concern.

Claim 47,49-50 & 52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over TREACY et al WO 0054591 in view of HACKETT et al 6955818 and PETRAS 5965137.

TREACY shows the instant compositions of amitraz and metaflumizone, with carriers, prepared as dilutions for application to kill agricultural and hygienic pests. These include (page 14, lines 3-7) flies, mosquitoes, wasps, and other animal pests. However, the IPM, DEET and cineole are not specified.

HACKETT shows 0.1-40% actives, including amitraz and IPM. IPM is shown at 80/20 (column 6, yop) carrier component. Carrier is shown as 60-99.9% (column 4, line 58-column 5, line 3). HACKETT shows IPM at 20%.

PETRUS also provides the instant components for ectoparasite protection-diethyl toluamide (column 2, lines 39-44,) IPM (column 3, lines 44-45) as skin penetrants, and

cineole as antiseptic and insect repellant (column 5, lines 45-53) at 5-20% of a topical composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use the synergistic combination shown particularly effective by TREACY to control flies, with carriers as shown by HACKETT to provide with IPM and additives as desired. Such additives are taught by PETRUS to include 5-20% cineole as penetration enhancer and insect repellant and with IPM. The components are art recognized, with artisans capable of admixing in appropriate concentrations to provide solution and dispersion of actives and with added cineole and diethyl toluamide and IPM at levels as of the instant.

Other actives and carriers are permitted, as PETRUS.

The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular species and application method of interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

The instant language is in open guise, the IPM and DEET are not specified as to concentration.

### ***Double Patenting***

Claim 49, 50, 52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-9 of copending Application No. 11/245579 IN us2006/0078585.. Although the conflicting claims are not identical, they are not patentably distinct from each other because The 11 ' application anticipates the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant's arguments filed 9/21/09 have been fully considered but they are not persuasive. As applicant argues, one would not optimize by increasing concentrations of actives. Examiner finds it obvious to the practitioner that given a demonstrated 100% kill at low concentrations applied to a species, higher concentrations would be obvious to test in a dosage range applied to other species not 100% killed at the initial low concentration. Clearly, concentrates of 100% actives, at the instant ratios of compound Ia to amitraz, or less than 100% with IPM additional active and solvents, are obtainable with minimal testing.

The fact that compositions are effective at high concentration is not surprising. The efficacy to animal pest is irrelevant to the application of the composition. Methods are not examined here.

Claim 46 is allowable, as the composition is 20% Ia, 10% amitraz, 20% IPM, and 10% cineola-all in diethyl toluamide, thus the composition is defined as 20+ 10 + 20 + 10 + 40 by subtraction of diethyltoluamide.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT A. WAX can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/  
Primary Examiner, Art Unit 1615

12/29/09